

**REMARKS**

Favorable action on the merits is solicited in view of the following remarks.

Claims 8-14 are pending in this application and stand rejected. The claims were last amended in the after final response dated January 5, 2009, which should be entered by the attached RCE, per US practice.

Below Applicants provide the additional arguments to supplement the January 5, 2009 response. It is believed that these arguments further support the positions in the January 5, 2009 response that: (i) the specification provides full written support for claims 11 and 14; and (ii) the claims 8-14 are novel and nonobvious over DESJONQUERES (US 6,001,378) in view of HIRAMA et al. (US 4,713,397) and ZAVERI et al. (US 6,376,557) as cited in the final Office Action.

Below is an evaluation of the formulation of the claimed compositions compared with other similar products.

Originality means that the claimed composition is peculiar or characteristic in that it contains intrinsic technical characteristics that are exclusive to it and not common to other products.

The compositions of independent claims 8, 11, and 14 are objectively different from many other similar products.

In this regard, the base for many hair products used to combat hair loss constitute the use of vasoactive substances,

such as nicotinate. Nicotinate stimulates vasodilatation and the passage of oxygen and nourishing substances to the hair bulb.

Other substances, which are sometimes added to these hair products, include: vitamins, microelements, amino acids and sulphides, in an attempt to provide the hair with substances that are used to reconstruct the keratin fibers that the hair stem is formed of.

Other products tend to exploit the presumed action of plant extracts, which boast, without any reliable demonstration, a stimulating action for hair growth.

In the claimed composition, not only is the formulation original for the functional substances that are used, but there is also a theoretic rational structure that has led the Applicants to the choice of the functional principles.

The aim of the formulation of the claims is to interfere with the numerous mechanisms that cause hair loss, but without exerting any local pharmacological or systemic action, which would be the case with an anti-hormone activity.

On analyzing the claimed formulation, it is found that the two amino acids used, hydroxyproline and aspartic acid, have the task of improving the environment that houses the hair follicle: the dermal connective tissue. This tissue houses the dermal papilla and its cells, including special modified fibroblasts which act and determine the activity of the follicle

and influence both positively and negatively the life of the hair to the extent they are called the hair pace-makers.

These two amino acids can cause an increase both in the number of fibroblast cells and in the biosynthesis of the factors produced by the dermal cells, like those that form the hair papilla, as has been demonstrated with in vitro tests on fibroblasts. This further supports Applicants' arguments in the last response that the specification discusses the effectiveness of hydroxyproline and aspartic acid by themselves (without being complexed with silanol) to treat/delay hair loss. Thus, it is again respectfully submitted that the specification reasonably contemplates the combination of hydroxyproline and aspartic acid together, not complexed with silanol, in the claimed composition for topical administration to treat/delay hair loss. This is further evidence that the written description rejection of claims 11 and 14 under 35 USC 112, first paragraph, should be withdrawn.

Furthermore, the instant specification discloses that when hydroxyproline and aspartic acid are complexed with an organic by-product of silicone (silanol), it forms a substance that acts by promoting fibroblast proliferation on one side and increases the crossed links between the collagen fibers that form the dermal tissue on the other side.

Silanol, when complexed with aspartic acid and hydroxyproline, is important to achieve those complex

mucopolysaccharides that are the fundamental substance in the derma.

This allows a positive interaction with the dermal tissue surrounding the hair, creating a microenvironment rich in substances that guarantee adequate support for hair growth and, at the same time, stimulates the dermal papillary cells that the impulse for hair re-growth depends on.

The claimed formulation also includes butyric acid and peptides that are rich in glutamine.

The addition of these two substances to the product satisfies the need to act on both the keratinisation process of the hair stem and to provide a highly energetic substratum that is useful for rapidly growing and differentiating cells, like those in the hair follicle.

In fact, butyric acid stimulates the activity of the transglutaminase enzyme that is needed in the epidermis and in the hair follicle for the correct keratinisation processes.

In particular, this enzyme is contained in the hair follicle in the internal epithelial sheath and it determines the formation of crossed links between the residual amino acids of lysine and glutamine among the structural proteins of the hair, strengthening the stem.

Thanks to the action of the transglutaminase on the glutamine, peptides rich in this amino acid have been included in the claimed formula, because glutamine is the main substratum

that the enzyme works on. Furthermore, this amino acid is a fundamental energy reserve for the cellular metabolism and is used when the source of glucose has run out.

To guarantee this backup energy (that is essential for cellular growth and differentiation), Applicants added yet another substance, panthenol, to the claimed formula. Panthenol is the essential constituent of Coenzyme A, and is a fundamental molecule for energetic metabolism in all cells of an organism, especially skin cells.

Based on the above, it is clear that Applicants formulated the preparation of claims 8, 11, and 14 with the precise aim of to act on the main mechanisms that cause hair loss, making precise rational choices on the basis of in-depth scientific knowledge. In fact, the claimed preparations were formulated and produced to carry out specific and particular actions, aimed at contrasting some of the pathogenic mechanisms that are responsible for hair loss.

In view of the above, it is believed that the claimed formulation is an original product that is very different from the common hair lotions used to combat hair loss. It is believed that such is further evidence that the claimed compositions are novel and non-obvious in terms of their final formulation, which was developed to reach the technical solution described above and reflected in independent claims 7, 11 and 14.

For these additional reasons, it is believed that the written description rejection of claims 11 and 14 and the obviousness rejection of claims 8-14 over DESJONQUERES, HIRAMA et al., and ZAVERI et al. are untenable and should be withdrawn.

It should be noted that Applicants will consider submitting an expert's opinion in a Rule 132 Declaration that discusses the above at a later date.

Having fully addressed all of the issues raised in the Office Action, it is respectfully submitted that the present application is in condition for allowance and early notice to that effect is hereby requested. If the Examiner has any comments or proposals for expediting prosecution, please contact the undersigned attorney at the telephone number below.

The Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 25-0120 for any additional fees required under 37 C.F.R. § 1.16 or under 37 C.F.R. § 1.17.

Respectfully submitted,

YOUNG & THOMPSON



---

Jay F. Williams, Reg. No. 48,036  
209 Madison Street, Suite 500  
Alexandria, VA 22314  
Telephone (703) 521-2297  
Telefax (703) 685-0573  
(703) 979-4709

JFW/ml